

Texas State Board of Pharmacy Webinar FAQs and Troubleshooting Tips

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Texas Pharmacy Law Update

Allison Vordenbaumen Benz, R.Ph., M.S.
Director of Professional Services
November 12, 2015



Goals

- Review recent changes to pharmacy rules;
- Review the most common Warning Notices Issued to Class A and Class C Pharmacies;
- Review pharmacy related legislation passed by the 2015 Legislature;
- Review some current issues facing the Board; and
- Answer your questions.



Board of Pharmacy Members

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Rules Adopted by the Board at the November 3, 2015 Meeting



Grounds for Discipline

- Effective Date: Late November 2015.
- It is a ground for discipline of a pharmacist or pharmacy technician if the individual exhibits abusive, intimidating, or threatening behavior toward a board member or employee during the performance of a member's or employee's lawful duties.



Pharmacist-in-Charge

- Effective Date: Late November 2015.
- A pharmacist-in-charge (PIC) of a Class A Pharmacy may not also be the PIC of a:
 - Class B Pharmacy; or
 - Class C Pharmacy in a hospital with 101 beds or more.



Administration of Immunizations and Vaccines

- Effective Date: Late November 2015.
- Before preparing an immunization/vaccine and between each patient contact:
 - Pharmacist must:
 - cleanse their hands with an alcohol-based waterless antiseptic hand rub; or
 - wash their hands with soap and water.
 - If gloves are worn, pharmacists must change gloves between patients.



Class A Pharmacies



Patient Counseling Regulations

- Effective Date: December 7, 2014.
- Patient counseling must be provided to new and existing patients of a pharmacy with each new prescription drug order.
- A new prescription drug order is one that has not been dispensed by the pharmacy to the patient in the same dosage and strength within the last year.



Patient Counseling Regulations (cont).

- Written information may now be provided to the patient in an electronic format, such as by e-mail, if:
 - The patient or patient's agent requests the information in an electronic format; and
 - The pharmacy documents the request.



Patient Counseling Regulations (cont).

- **Eliminated** the requirement for a pharmacy to:
 - Offer counseling on a refill prescription; and
 - Post a sign that said *"Do you have questions about your prescription? Ask the pharmacist."*



Transfer of Prescription Information

- Effective Date: December 7, 2014.
- Updated the transfer regulations to allow for the:
 - Electronic transfer of records;
 - Electronic transfer of multiple or bulk prescription records between two pharmacies; and
 - Match DEA's regulations.



Class C Pharmacy Regulations



Number of Beds in a Hospital

- Effective Date: December 7, 2014
- Number of Beds – The total number of beds is determined by the number of:
 - Beds that the hospital is licensed for by the Texas Department of State Health Services; or
 - Inpatients admitted during the previous calendar year divided by 365 (or 366 if the previous calendar year is a leap year).



Pharmacists and Pharmacy Technicians



Pharmacist's Continuing Education

- Effective Date: March 17, 2013.
- Pharmacists can receive credit for programs approved by AMA as Category 1 CME.
- Pharmacists must report 1-hour of CE related to Texas Pharmacy Laws or Regulations on renewals received after 1/1/15.



Pharmacy Technician's Continuing Education

- Effective Date: June 12, 2013.
- Pharmacy Technicians must report 1-hour of CE related to Texas Pharmacy Laws or Regulations on renewals received after 1/1/15.



Pharmacy Technician's Continuing Education (cont.)

- Effective Date: September 14, 2015.
Amendments to §297.8 (Continuing Education) rules to:
 - Decrease the number of in-service hours from 10 to 5 hours;
 - Clarify the requirements for CE; and
 - Clarify the types of programs that count for continuing education.



Licensing Fee Changes

License	Renewal Fee Effective <u>10/1/15</u>	Change
Pharmacist	\$276	\$25 decrease
Pharmacies	\$452	\$80 decrease
Pharmacy Technicians	\$77	\$19 decrease
Pharmacy Technician Trainees	\$52	\$10 decrease



Conditions Receiving "Warning Notices" FY2014



Number of Inspections

Class	FY2014	% of FY2014 Inspections
Class A Pharmacies	1,176	69%
Class A-S	4	<1%
Class B Pharmacies	3	<1%
Class C Pharmacies	446	26%
Class C-S	4	<1%
Class D Pharmacies	56	3%
Class F Pharmacies	5	<1%
Class G Pharmacies	4	<1%
Totals	1,698	100%



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Warning Notices

Class	# Pharmacies Receiving WN	% Receiving WN
Class A	536	61%
Class A-S	3	<1%
Class B	0	N/A
Class C	316	36%
Class C-S	4	<1%
Class D	18	2%
Class F	2	<1%
Class G	0	N/A
Totals	879	100%



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Most Common Warning Notices (All Classes of Pharmacy)

Violation	Number of WN Issued*	% of Total WN
Sterile Product	844	29%
Pharmacy Technician	398	14%
Records	273	9%
Drug Stock/Environment	271	9%
Prescriptions	160	5%
Inventory	157	5%
OBRA	152	5%

* One pharmacy may receive multiple Warning Notice violations.



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Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Sterile Product		844
No/Incomplete QA/QC	141	
No/Incomplete P&P Manual	128	
No/Inadequate Preparation Area	358	
IV Preparation	196	
No DUR	15	
Cytotoxic/Bio Procedures	6	



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TEXAS STATE BOARD OF PHARMACY

Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Pharmacy Technicians		398
No/Incomplete Training	367	
No/Improper Supervision	10	
Improper Registration	16	
No Name Tags	5	



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Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Records		273
Records Not Available	90	
Absence of R.Ph. Record	15	
Rx Not Separated	7	
Rx Records Not Numerical Order	5	
Improper Transfer of RX copies	5	
Invoices Not Separated/Retrievable	52	
Records for Non-Sterile Compounds	77	
No Written Information on RX	22	



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Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Drug Stock/Environment		271
Improper Environment	100	
Out-of-Date Drug Stock	83	
Security	36	
Unsanitary	30	
Improper Drug Storage	16	
Area for Non-Sterile Compounding	2	
Violation of Limited Formulary	4	



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Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Prescriptions		160
Lack Proper Information	77	
Prescription Label Incorrect	68	
Official Rx Non-Compliance	15	



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Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Inventory		157
No Annual Inventory	48	
No Change of Ownership Inventory	6	
No Change of PIC Inventory	32	
Incomplete Inventory	68	
No Perpetual inventory (Class C)	2	
Improper Drug Destruction	1	



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Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
OBRA		152
Written Information Not Provided	22	
No Patient Counseling	117	
PMR Absent or Incomplete	13	



Violations NOT Resulting in Warning Notices

- Individuals performing technician duties without an active registration.
- Technicians performing technician duties with no pharmacist on site.
- Technicians performing pharmacist-only duties with no pharmacist on site (results in emergency temporary suspension hearing).
- Pharmacists who do not verbally counsel a patient on a new prescription.



Violations NOT Resulting in Warning Notices

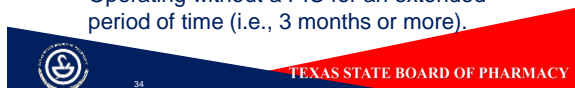
- Pharmacy is not able to produce 2 consecutive annual inventories.
- PIC falsifies response to a Warning Notice.
- Pharmacies dispensing/shipping prescription drugs into other states without holding a pharmacy license in that state.
- Pharmacies compounding sterile preparations without proper licensure (e.g., Class A who should have a Class A-S pharmacy license).



Violations NOT Resulting in Warning Notices

Egregious Conditions

- Dispensing CII pursuant to prescriptions not issued on an Official Form;
- Excessive quantity of out-of-date stock (i.e., more than 25% of the inventory);
- Pharmacy closed and did not notify TSBP of closing;
- Operating without a PIC for an extended period of time (i.e., 3 months or more).



Violations NOT Resulting in Warning Notices

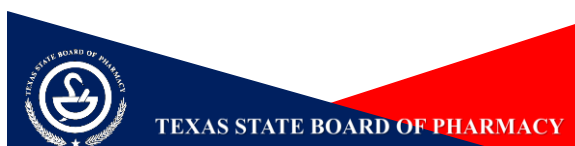
Continuing threat – For example:

- Impaired pharmacist on duty; or
- Sterile compounding pharmacies who have extensive non-compliance with Board Rule 291.133 and will not voluntarily agree to “*cease and desist*” sterile compounding until conditions have been corrected.

Both of These Scenarios Would Result In An Emergency Temporary Suspension Hearing.



Pharmacy Related Legislation Passed by the 2015 Legislature



S.B. 195 by Sen. Schwertner

- Effective Date: 6/20/2015 for some provisions and 9/1/2016 for others.

- This bill:

- Allows the Board, on or after 6/20/2015 to:
 - Adopt rules to implement the PMP and certain other provisions related to prescriptions in the Controlled Substances Act.
 - Sign a contract with a vendor to operate the PMP.
 - Call a meeting of the Prescription Monitoring Work Group.



S.B. 195 by Sen. Schwertner (cont.)

- On 9/1/2016:
 - The Board will establish a program to fund the Prescription Monitoring Program (PMP) through a surcharge on the license fees of persons authorized to access the PMP.
 - The PMP is transferred from the DPS to TSBP.**
 - The Controlled Substance Registration program is abolished.



S.B. 460 by Sen. Schwertner

- Effective Date: 9/1/2015.
- This bill amends the Pharmacy Act to:
 - Allow the Board to inspect financial records relating to the operation of a pharmacy only in the course of an investigation of a specific complaint.
 - Require a pharmacy to file an application to change location at least 30-days prior to the move.



S.B. 460 by Sen. Schwertner (cont.)

- Amends the Pharmacy Act to:
 - Eliminate the Generic Substitution Sign and modify the requirement for the Complaint Notification to allow electronic posting..
 - Specify that a pharmacy license may not be renewed if it has expired for 91 days or more.



S.B. 460 by Sen. Schwertner (cont.)

- Amends the Pharmacy Act for Class E Pharmacies to:
 - Allow the Board to discipline the pharmacy if it has been disciplined in their state.
 - Prohibit a person from owning the pharmacy if their R.Ph. license was revoked, suspended, restricted, surrendered in another state.
 - Require the pharmacy to have a Texas licensed pharmacist serve as the PIC for the Texas license.



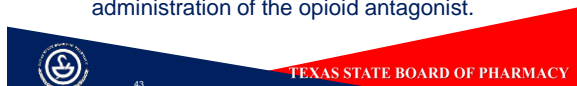
S.B. 1462 by Sen. Royce West

- Effective Date: 9/1/2015.
- This bill adds a new Subchapter E. Opioid Antagonist to the Dangerous Drug Act that:
 - Allows Drs, without risk of discipline, to prescribe/ issue a standing order for an opioid antagonist to:
 - A person at risk of experiencing an opioid-related drug overdose; or
 - A family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related drug overdose.



S.B. 1462 by Sen. Royce West (cont.)

- Allows a R.Ph. to dispense or not dispense an opioid antagonist under a valid Rx for without risk of criminal/civil liability or disciplinary action for:
 - dispensing or failing to dispense the opioid antagonist; or
 - if the R.Ph. dispenses an opioid antagonist, any outcome resulting from the eventual administration of the opioid antagonist.



H.B. 751 by Rep. Zerwas

- Effective Date: 9/1/2015.
- The bill allows the substitution of interchangeable biological products.
- Interchangeable biological products are those rated equivalent by FDA (Orange Book and the Purple Book).



H.B. 751 by Rep. Zerwas (cont.)

- The bill specifies that not later than the 3rd business day after dispensing the R.Ph. must “*communicate*” to the prescribing Dr. the name of the product provided and the manufacturer or NDC number.
- The bill outlines several methods to notify the prescriber.



H.B. 751 by Rep. Zerwas (cont.)

- Notification is not required if:
 - There is no interchangeable biological product approved by FDA; or
 - A refill prescription is not changed from the product dispensed on the prior dispensing.
- The notification section of the bill expires on 9/1/2019.



H. B. 1550 by Zerwas/Kolkhorst

- Effective Date: 9/1/2015.
- This bill amends the Pharmacy Act to:
 - Allow a R.Ph.s to administer epinephrine, using an auto-injector, to a patient in an emergency situation.
 - Specify a R.Ph. may not receive remuneration for the administration of epinephrine but may seek reimbursement for the cost of the epinephrine auto-injector.



H. B. 1550 by Zerwas/Kolkhorst (cont.)

- This bill amends the Pharmacy Act to:
 - Specify that a R.Ph. who administers epinephrine through an auto-injector device is not liable for civil damages if the pharmacist acts in good faith and complies with Board rules.



S.B. 1243 by Sen. Burton

- Effective Date: 1/1/16.
- This bill establishes a Prescription Drug Donation Pilot Program in the DSHS.
- The Program must be established in one or more cities with a population of more than 500,000 but less than one million.



SB 1243 by Sen. Burton (cont.)

- A Dr., Phcy. Nursing Home, Mfr, etc., may donate non-controlled Rx drugs to DSHS.
- The donated drugs may be provided or administered to patients only by a:
 - Charitable medical clinic;
 - Dr's office for patients who receive assistance from an indigent health care program; or
 - Licensed health care professional in a penal institution.



SB 1243 by Sen. Burton (cont.)

- DSHS must establish and maintain an electronic database which:
 - Lists the name and quantity of each drug donated to DSHS under the program; and
 - Allows a charitable medical clinic, physician, or other licensed health care professional to search for and request drugs.



SB 1243 by Sen. Burton (cont.)

- The entity providing or administering the drug may charge a nominal handling fee in an amount prescribed by DSHS rule.
- DSHS must adopt rules for by 12/1/2015.



S.B 1697 by Sen. Huffman

- Effective Date: 9/1/2015.
- The bill makes confidential any information identifying:
 - Any person who participates in an execution procedure; and
 - Any person or entity that manufactures, compounds, prescribes, dispenses, or provides a substance or supplies used in an execution.



Current Issues



Sunset Review

- Texas Pharmacy Act, Sec. 551.005.
Application of Sunset Act.
 - The Texas State Board of Pharmacy is subject to Chapter 325, Government Code (Texas Sunset Act). Unless continued in existence as provided by that chapter, the board is abolished and this subtitle expires September 1, 2017.



Sunset Review Time Line

- August 2015.
 - TSBP prepares a Self-Evaluation Report.
- October 2015 – March 2016.
 - Sunset staff reviews the agency.
- Late March 2016.
 - Sunset's confidential report issued followed by a joint meeting with TSBP to discuss recommendations, followed by Sunset's formal request for agency written response.



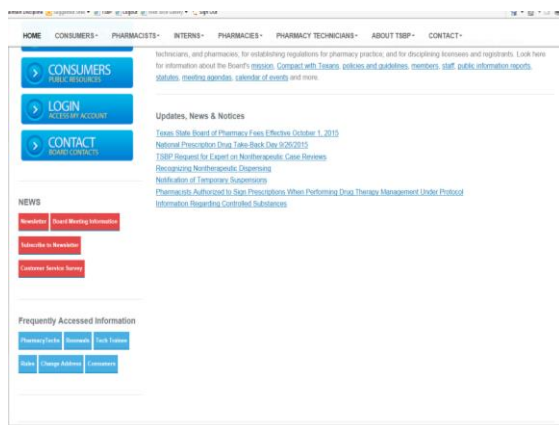
Sunset Review Time Line (cont.)

- April 2016.
 - Sunset Staff Report Published.
- May 2016.
 - Sunset Commission holds a Public Hearing to receive public comment on the agency.
- Summer 2016.
 - Commission Decisions are issued.
- January – May 2017.
 - 2017 Legislative Session



TSBP Website

www.pharmacy.texas.gov



Final Reminders (Part I)

- If you have any compliance-related questions, please call the TSBP Compliance Line at 512-305-8070.
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Questions?

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